

in interstate commerce without labeling stating the conditions and purposes for which the article was intended; and that, in such case, the article would be misbranded under 502 (f) (1), in that its labeling would fail to bear adequate directions for use because of the omission from such labeling of statements of the conditions and purposes for which the article was intended.

The complaint alleged further that the defendants were well aware that their activities were violative of the Act; that 10 seizures had been made of the article since 1945, 2 of which were contested; and that 3 notices of hearing were issued during 1946 and 1947, based on essentially the same charges of misbranding under 502 (a) as alleged in the complaint.

DISPOSITION: On 7-15-55, with the consent of the defendants, a preliminary injunction was entered. On 6-14-56, the defendants having consented, a decree of permanent injunction was entered enjoining the defendants from causing the introduction and delivery for introduction into interstate commerce of *Blake's Mineral Compound* or any other drug of similar composition which is misbranded as follows:

(a) under 502 (a) by reason of any representation or suggestion in the labeling of such article that the article is effective for treating and preventing bloat or the effects of poison weeds in sheep and cattle, or by reason of any other false or misleading representation or suggestion in the labeling of the article;

(b) under 502 (a) by reason of any representation which suggests or implies that the article furnishes essential minerals required by sheep and cattle; or

(c) under 502 (f) (1) because the labeling of such article fails to state all the conditions and purposes for which the article is intended.

5199. Piperate tablets and powder. (F. D. C. No. 39077. S. Nos. 51-541 M, 51-553/5 M, 51-577 M, 51-579/80 M.)

QUANTITY: 25 100-tablet btls., 3 1,000-tablet btls., 19 4-oz. btls., and 20 1-lb. btls. at Denver, Colo.

SHIPPED: Between 11-29-55 and 4-30-56, from Fort Dodge, Iowa, by Fort Dodge Laboratories, Inc.

LABEL IN PART: (Btl.) "Fort Dodge * * * Piperate Tablets * * *
Each tablet contains: Piperazine Adipate . . . 250 mg." and "Fort Dodge
Piperate Piperazine Adipate Active ingredient: Piperazine Adipate, 100%."

LIBELED: 5-24-56, Dist. Colo.

CHARGE: 502 (a)—the statement on the label of the article (tablets), when shipped, "Indications: For removal of * * * hookworms (*Uncinaria stenocephala*) in dogs" was false and misleading since the article was not effective for the removal of hookworms infesting dogs in this country; and the label of the article (powder), when shipped, contained statements which represented and suggested that the article was an adequate and effective treatment for nodular worms in horses and pinworms and strongyles in swine, cattle, and poultry, which statements were false and misleading since these animals are not subject to such conditions.

DISPOSITION: 9-24-56. Consent—claimed by Fort Dodge Laboratories, Inc., and relabeled.

5200. Pratts In-Tes-Trol. (F. D. C. No. 38990. S. No. 43-953 M.)

QUANTITY: 9 100-lb. drums at Springdale, Ark.

SHIPPED: 3-1-56, from Hammond, Ind., by Pratt Food Co., Inc.

LABEL IN PART: (Drum) "Pratts In-Tes-Trol (Powder) * * * For Chickens And Turkeys Of All Ages Active Ingredients: Methylosanline (Gentian Violet) Copper Sulfate (Hydrated) 40% Ferrous Sulfate (Copperas) Zinc Sulfate, Manganese Sulfate, Tartaric Acid Inert Calcium Sulfate (Nature) 50%."

ACCOMPANYING LABELING: (Leaflet enclosed in each drum) "Pratts In-Tes-Trol (Powder) For Chickens And Turkeys Of All Ages."

LIBLED: 3-30-56, W. Dist. Ark.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for overcoming and preventing mycosis in poultry.

DISPOSITION: 5-19-56. Default—destruction.

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¹ (5198) Injunction issued.

² (5163) Seizure contested. Contains opinion of appellate court and decree of condemnation of district court.

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5201-5220

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They relate to drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or trial; (2) criminal proceedings which were terminated with a plea or verdict of guilty; (3) injunction proceedings terminated with the entry of an injunction. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., July 25, 1958.

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 5201, 5217; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5201; cosmetic, actionable under the drug provisions of the Act, No. 5217.

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS 5201-5220**

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; Section 501 (d), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b) (1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5201. R-20 hair treatment. (F. D. C. No. 39640. S. No. 40-913 M.)

QUANTITY: 2 btls., containing 20 oz. total, of *R-20 hair treatment*, and 2 jugs, 1 containing 1 gal. and the other containing 28 oz., of diluted *R-20 hair treatment*, at Minneapolis, Minn.

SHIPPED: 8-23-56, from Rouses Point, N. Y., by Dr. R. E. Liefmann.

LABEL IN PART: (Btl.) "R-20 Batch #17, 8-27-56 Regular"; (jug) "the Frommes formula R-20 by Frommes Scalp Specialists Minneapolis."

RESULTS OF INVESTIGATION: Analysis showed that the drug consisted of an isopropyl alcohol solution of alpha-estradiol. The drug was shipped unlabeled, and, upon arrival, the handwritten bottle labeled "R-20 Batch #17 8-27-56 Regular" was affixed by the consignee, Frommes Method, Inc.

The diluted material was prepared by the consignee by adding an additional quantity of isopropyl alcohol to a portion of the shipped drug. The "Frommes formula R-20" labels were printed locally for the consignee, who applied them to the diluted material.

LIBELED: 10-24-56, Dist. Minn.

CHARGE: 502 (b) (1)—the label of the article, when shipped, failed to bear the name and place of business of the manufacturer, packer, or distributor; 502 (e) (2)—the article was fabricated from 2 or more ingredients, and its label, when shipped, failed to bear the common or usual name of each active ingredient; 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use; and 503 (b) (4)—the article was a drug which was not safe for use except under the supervision of a practitioner li-